Compendium
Transparent Drug System for Patients Act, 2006

Background

The publicly funded drug system in Ontario provides more than $3 billion of drugs to 2.8 million eligible people through the Ontario Drug Benefit (ODB) program, as well as an additional $280 million through other specialized programs. Ontario intends to continue funding certain drugs, however, the rising costs of prescription drugs and inefficiencies in the current drug system are eroding the long-term sustainability of the province's publicly funded drug programs.

The Drug System Secretariat was established by the Ministry of Health and Long-Term Care (the Ministry) at the direction of the Minister of Health and Long-Term Care (the Minister), to conduct an objective, system-wide review of Ontario's entire drug system. The Secretariat conducted research with experts worldwide, studied best practices in other jurisdictions, and extensively consulted stakeholders from across the provincial drug system. Stakeholders included patients, professional organizations, industry organizations, brand name and generic manufacturers, hospitals, wholesalers, private insurers, major employers and the general public.

Through the Secretariat's work, several concerns were raised including the:

- need for greater transparency and accountability in the supply chain for drug products in Ontario to ensure that government is getting value for money;
- need for greater transparency in the government decision making process regarding the funding of drugs;
- opportunities for government to achieve better health outcomes and increase access to drugs;
- need for greater collaboration with the private sector to help manage drug costs, to enable employers to remain economically competitive in Ontario; and
- need for government to be a more active consumer and to leverage its purchasing power.

Informed by these and other concerns, the Secretariat developed a package of recommendations for reform of the provincial drug system. Changes to Ontario's drug system will result in an improved and more aggressively managed provincial drug system framework through integrated policy and legislative and regulatory changes. The framework considers five key areas – pricing and reimbursement of drug products; access to drug products; need for more appropriate use partnerships; innovation; and, strengthening the governance and operations of Ontario's drug system.

The *Transparent Drug System for Patients Act, 2006* incorporates the necessary legislative changes required to implement the drug system strategies.

Summary

Part I of the *Transparent Drug System for Patients Act, 2006* [the Act] makes amendments to the *Drug Interchangeability and Dispensing Fee Act* [DIDFA]. The amendments to the DIDFA transfer the previous function and power of the Minister under the DIDFA to make regulations designating products as interchangeable with others and the function and power of the Lieutenant Governor in Council [LGIC] to remove designations of interchangeable products by way of regulation, to the executive officer of the Ontario public drug programs (the position of the executive officer is created by amendments to the *Ontario Drug Benefit Act* [ODBA]). The executive officer may designate products as interchangeable and remove

such designations by publishing updates on the Formulary, a defined term in the ODBA. Conditions for designating products as interchangeable continue to be set out in regulations.

The executive officer is required to follow the same requirements for interchangeability as those that applied to the powers of the Minister and the LGIC.

One requirement for interchangeability is amended to include that products may be designated as interchangeable not only where they have the same active ingredients in the same dosage form, but also where they have similar active ingredients in a similar dosage form. The Minister will be enabled to make a regulation, before the Minister's functions and powers are transferred to the executive officer on October 1, 2006, to designate products as interchangeable where they have similar active ingredients and are in a similar dosage form, as soon as the Act receives Royal Assent. This amendment to the Minister's regulation-making authority is repealed once the amendments pertaining to the executive officer come into force.

The DIDFA is further amended to prohibit manufacturers from providing a rebate, a defined term, to wholesalers, operators of pharmacies, companies that own, operate or franchise pharmacies or to their directors, officers, employees or agents with respect to interchangeable products or those products in respect of which the manufacturer has made an application to the executive officer for designation as interchangeable. The DIDFA is also amended to prohibit any person from accepting a rebate, directly or indirectly. The executive officer is empowered to make an order requiring the manufacturer to pay an amount as specified in the DIDFA, which reflects the value of the rebate, to the Minister of Finance. The amendments set out the calculation of the amount owing to the government, the process by which the manufacturer is to be notified of the amount payable, reconsideration of the amount, and steps that the executive officer may take for non-compliance.

Part II of the Act makes amendments to the ODBA. It includes Principles pertaining to the public drug system. It creates the position of the executive officer of the Ontario public drug programs with the functions and powers as described in the ODBA. Most of the functions and powers that previously rested with the Minister under the ODBA are transferred to the executive officer. The amendments further describe the Formulary (the drug list that the executive officer is required to keep, maintain and publish) and its contents. The Formulary is required to be published on the Ministry's website.

Updating the Formulary is no longer dependent on the filing of regulations, but rather, the executive officer – and no longer the Minister or LGIC – has authority to designate listed drug products on the Formulary and remove products from the Formulary. Conditions for listing drug products continue to be as prescribed in regulations; however, the executive officer, and not the LGIC, has the authority to set out specified clinical criteria that must be met as a condition for payment in respect of specified drug products or classes of drug products.

The drug benefit price in respect of a listed drug product, previously set out in regulations, may be determined by the executive officer, as agreed to by the executive officer and the manufacturer, and published in the Formulary, in accordance with provisions in the ODBA. The drug benefit price for products that are not on the Formulary, but for which the executive officer has made the ODBA apply through an exceptional access program, may also be determined by the executive officer, in accordance with the regulations. The executive officer may establish rules, criteria and procedures that a manufacturer must follow in submitting requests for changes to the drug benefit price.

The amendments to the ODBA include a number of regulation-making changes that enable, among other things, operators of pharmacies to be paid for professional services; the setting

out in regulations requirements pertaining to the acquisition cost of a drug product for the operator of a pharmacy; the creation of regulations to address alternative payment mechanisms to operators of pharmacies for certain classes of eligible persons; and the setting of a mark up of the drug benefit price that the executive officer will pay under the ODBA.

The ODBA will allow pharmacies that operate in public hospitals to charge the same dispensing fee as pharmacies in the community. This amendment comes into force on Royal Assent.

The ODBA is amended to prohibit manufacturers from selling a listed drug product at a price higher than its drug benefit price as listed in the Formulary. Manufacturers are also prohibited from providing a rebate, a defined term, to wholesalers, operators of pharmacies, companies that own, operate or franchise pharmacies or to their directors, officers, employees or agents with respect to listed drug products, listed substances and designated pharmaceutical products or those products in respect of which the manufacturer has made an application to the executive officer for the listing of a drug product in the Formulary. The ODBA further prohibits any person from accepting a rebate, directly or indirectly. The executive officer is empowered to make an order requiring the manufacturer to pay an amount as specified in the ODBA. The ODBA also sets out how the amount that exceeds the drug benefit price is determined and the calculation of the value of the rebate, including the process by which the manufacturer is to be notified of the amounts owing, the reconsideration of the amounts, and steps that the executive officer may take for non-compliance. The procedures for enforcement are similar to those set out in DIDFA amendments.

The ODBA is further amended to enable the executive officer, for the purpose of determining compliance with the ODBA or the DIDFA, require a manufacturer, wholesaler, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies to provide information, other than personal information, to the executive officer, either in response to a specific request or at regular intervals. The executive officer may set out the time at which and the form in which, the information must be provided.

Part III of the Act sets out that all provisions of the Act come into force on October 1, 2006, except the commencement section and those sections pertaining to the immediate change to the provisions in the DIDFA that refer to same or similar active ingredients and same or similar dosage form, and the provision in the ODBA with respect to the hospital pharmacy dispensing fee come into force on Royal Assent.

Part I: Amendments to the Drug Interchangeability and Dispensing Fee Act

Section 1

Definitions
The section changes the term “designated” from meaning “designated in regulations” to meaning “listed in the Formulary”.

This section also defines the terms: “executive officer” and “Formulary”. “Executive officer” means the executive officer of the Ontario public drug programs appointed under the ODBA; and “Formulary” means the Formulary that the executive officer is required to keep, maintain and publish under the ODBA.

Section 2

Executive Officer and interchangeability
The executive officer is empowered to designate products as interchangeable with other products on the Formulary.

The Formulary and interchangeability
The effective date that a product becomes interchangeable with another or ceases to be interchangeable is as set out in the Formulary.

Requirements for interchangeability
The executive officer may t designate a product as interchangeable with another if the executive officer does not consider it in the public interest, but shall not do so if:

- The product does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or
- The conditions set out in regulations for designation have not been met.

Ceasing to be interchangeable
The executive officer may remove a product's designation of interchangeability if:

- Denying or removing the designation would be in the public interest;
- The drug does not meet the conditions set out in the regulations for designation; or
- The manufacturer has not complied with an order under the rebate section.

Modification
Where a designation is modified, its effective date is as set out in the Formulary.

Transitional
A product that was interchangeable with another product immediately before these amendments come into force will continue to be interchangeable with that product until the executive officer removes its interchangeability designation.

Section 3

Selection of interchangeable product
Where a prescription directs the dispensing of a product that is not an interchangeable product, this provision enables the dispenser to dispense an interchangeable product that contains a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the prescribed product. Previously, drugs needed to have the same active ingredients and be in the same dosage form in order to be interchangeable with each other. The change is consistent with the necessary conditions for interchangeability listed in section 2.

Section 4

Rebate, etc.
This section prohibits manufacturers from providing a rebate to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents for any drugs that are designated interchangeable or being considered for designation as interchangeable.

May not accept rebate
This section prohibits any person from accepting a rebate, directly or indirectly.

Executive officer may make an order
The executive officer may order manufacturers to pay the government an amount equal to the amount contrary to this section.

Calculation
The calculation of the amount owing to the government because of rebates is set out as follows:

- The expected cost for a drug product or group of drug products provided by the manufacturer to the wholesaler or pharmacy is based on the drug benefit price for that drug(s) multiplied by the amount of product the wholesaler or pharmacy received from the manufacturer.
- The payment amount to government is the difference between the expected cost noted above and the actual cost to the wholesaler or pharmacy which includes the impact of any price reductions, free goods, or direct payments by the manufacturer, as examples.

Reconsideration
The manufacturer may submit evidence to the executive officer that the amount calculated is not correct or that the manufacturer has not provided a rebate, within 14 days of being served with the order, and the executive officer is required to reconsider the order.

Actions of executive officer after reconsideration
After reconsidering the order, the executive officer may affirm, rescind or vary the order.

Executive officer may act
Where the manufacturer has not complied with an order within 14 days of being served with it, or once the order has been affirmed or varied, and the manufacturer still has not complied with it, the executive officer may issue a further order for compliance, or the executive officer may do one or both of the following until the manufacturer pays:

- If the product is an interchangeable product, remove the drug product's designation as interchangeable
- refuse to consider the manufacturer's other drug products for future designation as interchangeable, for future designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

Limit on reconsideration
The manufacturer does not have another opportunity to have a further order reconsidered.

Required notice
The executive officer must give 30 days notice before the executive officer may refuse to consider the manufacturer's other drug products for designation as interchangeable, for designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

Definition
"Rebate" includes, but is not limited to, currency, discounts, refunds, free goods or travel and any benefit set out by regulation. Regulations may explain what is not a rebate. A rebate does not include a discount for prompt payment offered in the ordinary course of business.

"Drug Benefit Price" is defined, for the purpose of the section pertaining to rebates, as including the price submitted by the manufacturer under the regulations, for those products that are not intended to be listed as a benefit under the ODBA and for those products that

are intended to be listed as a benefit, but have not been listed as yet, the price submitted by the manufacturer.

Rules re section 12.1
The executive officer is required to provide an order or a notice in a manner as set out in this section.

Same, publication of enforcement action
The executive officer may publish on the Ministry's website:
- the corporate names of manufacturers who are subject to a payment order or a measure to compel compliance; and,
- any information about the enforcement action that the executive officer believes is appropriate.

No appeal
There is no appeal, other than as provided in this section, from a decision or action of the executive officer to order payment or compel compliance with a payment order.

SPPA does not apply
The executive officer's power to order payment or to compel compliance with a payment order is not subject to the *Statutory Powers and Procedure Act.*

Section 5

Subsection 5(1)
This amendment enables the LGIC to define any word or expression used, but not specifically defined in the DIDFA.

Subsection 5(2)
This broadens the description of interchangeable by providing that interchangeable drugs can have the **same or similar** active ingredients in the **same or similar** dosage form. Previously, drugs needed to have the **same** active ingredients in **same** dosage form in order to be interchangeable with each other. This amendment applies to the Minister's authority to make regulations designating a product as interchangeable with one or more other products.

This change comes into force on Royal Assent.

Subsection 5(3)
This subsection removes the Minister's ability to make regulations designating interchangeable products (as amended in subsection 5(2), above), including the LGIC's power to make regulations removing designations of interchangeability. The executive officer will now exercise these powers at his or her discretion and interchangeability designation will no longer require regulations.

This amendment comes into force on October 1, 2006.

Subsection 5(4)
This subsection empowers the LGIC to make a regulation that can be applied retroactively so that its provisions may be effective from a date before the date the regulation is filed.

Part II: Amendments to the Ontario Drug Benefits Act

Section 6

Principles
This section sets out principles recognized in the ODBA. The principles include a commitment to a public drug system that:

- aims to meet the needs of Ontarians, as consumers and taxpayers
- aims to involve consumers and patients in a meaningful way
- aims to operate transparently, to the extent possible for all persons with an interest in the system
- aims to achieve value-for-money and ensure the best use of resources at every level of the system
- makes funding decisions for drugs on the best clinical and economic evidence available, that will be openly communicated to the extent possible

Section 7

Definitions
The section changes the term "designated" from meaning "designated in regulations" to meaning "designated in the Formulary by the executive officer".

"Prescribed" is defined as "prescribed by regulations."

"Minister" is defined as the Minister of Health and Long-Term Care or any other Cabinet member assigned to administer the ODBA.

This section also defines "executive officer" and "Formulary. "Executive officer" means the executive officer of the Ontario public drug programs appointed under the ODBA; and the "Formulary" means the Formulary that the executive officer is required to keep, maintain and publish under the ODBA.

Section 8

Executive Officer
This section creates the position of an executive officer for the Ontario public drug programs. The LGIC will appoint the executive officer.

Functions and powers
The Act sets out the functions and powers of the executive officer, most of which were formerly exercised by the Minister or the LGIC.

Specifically, the Act empowers the executive officer to:

- administer the Ontario public drug programs
- keep, maintain and publish the Formulary
- designate products as listed drug products, listed substances and designated pharmaceutical products for the purpose of the ODBA and to remove or modify those designations
- designate products as interchangeable with other products under the DIDFA and to remove or modify those designations
- negotiate agreements with manufacturers of drug products, including the drug benefit price for listed drug products
- negotiate drug benefit prices for listed substances with suppliers
- set drug benefit prices for designated pharmaceutical products
- dictate the format in which the information he or she requests must be communicated
-

- make payments under the Ontario public drug programs
- grant individual authorization under an exceptional access program for drugs that are not on the Formulary
- set payment amounts and disburse payments for the professional services that pharmacy operators provide
- perform any other functions authorized by law

The LGIC may make regulations to clarify, modify, restrict or add to the functions and powers of the executive officer.

Formulary
The executive officer must keep, maintain and publish a Formulary.

Contents, other information
The Formulary will set out:
- listed drug products and substances
- drug benefit prices
- interchangeable products
- any other information required by law
- any other information the executive officer desires to add

Publication
The executive officer must publish the Formulary on the Ministry's website, but may also publish it in any other format.

Where conflict
Formulary information on the Ministry website takes precedence over information in any other format, if there is a conflict.

Listing
A product becomes a 'listed drug product' on the effective date of its being designated in the Formulary and ceases to be such a product on the effective date of that designation being removed.

Requirements for listing
The executive officer may designate a drug product in the Formulary where the executive officer considers is in the public interest to list but shall not do so if the conditions that are set out in regulations have not been met

Modification
Where a designation is modified, its effective date is as set out in the Formulary.

Transitional
A drug product that was a listed drug product before the amendments come into force will continue to be a listed drug product until the executive officer removes it from the Formulary.

Section 9

Technical amendment
This section replaces the word "designated" with "prescribed." "Prescribed" has replaced "designated" in this Act as the word that denotes something in regulation.

Section 10

Subsections 10(1), 10(2), 10(3) and 10(4)
These subsections transfer powers and duties related to managing the Formulary from the Minister to the executive officer. The changes replace the term "Minister with "the executive officer" throughout.

Prescribed conditions for acquisition cost
This subsection includes an ability to set out in regulations conditions pertaining to the acquisition cost of a listed drug product.

Section 11

Payment of claim of operators
This amendment transfers the duty to pay pharmacy operators' claims from the Minister to the executive officer.

Alternative payments
This provision permits regulations creating alternative payment mechanisms for pharmacy operators for certain classes of eligible persons, such as long-term care facility residents.

Transitional
Any alternative payment agreement between the Minister and pharmacy operator that was in effect immediately before these amendments come into force will continue, with the executive officer substituted for the Minister, until terminated.

Transfer of duty
This subsection transfers the duty to pay physicians' claims from the Minister to the executive officer.

Section 12

Amount executive officer to pay
This amendment reflects the fact that the duties relating to claims payment are being transferred from the Minister to the executive officer.

The drug benefit price will no longer be prescribed in regulations, but will be determined by the executive officer, in accordance with provisions in the ODBA.

This section further replaces the word "designated" with "prescribed." "Prescribed" has replaced "designated" in this Act as the word that denotes something in regulation.

Subsections 12(2) and 12(5)
These subsections transfer duties relating to dispensing fees from the Minister to the executive officer.
Subsection 12(3)
This subsection repeals the authority to set different dispensing fees for hospital pharmacies from other pharmacies in the community.

Acquisition cost
This subsection adds an ability to set out in regulations conditions on the acquisition cost of a listed drug product for an operator of a pharmacy.

Section 13

This section repeals section 8. That ODBA section is now section 16.

Section 14

Transfer of power
This section transfers the power to make agreements with suppliers of listed substances from the Minister to the executive officer.
The section also transfers the ability to pay suppliers from the Minister to the executive officer.

Transitional
Any agreement between a supplier and the Minister made before these amendments come into force continues, with the executive officer substituted for the Minister, until terminated.

Sections 15, 16, 17, 18, and 24

Administrative changes
These sections make a number of technical changes that reflect the transfer of powers over the Ontario public drug programs from the Minister to the executive officer. The changes replace the term “the Minister” with “the executive officer” throughout.

Section 19

This section regulates the supply of a listed drug product at the drug benefit price and rebates.

New section 11.4:
Supply to be at drug benefit price
This section prohibits manufacturers from charging more than the price that is the drug benefit price as listed in the Formulary for listed drug products.

Agreement not to exceed drug benefit price
Manufacturers who agree to a drug benefit price with the executive officer must agree to honour that agreement.

Executive Officer may make order
The executive officer may order a manufacturer to pay the government an amount calculated under the ODBA for the price charged in excess of the agreed to drug benefit price.

How amount calculated
The amount the manufacturer is required to pay is determined by the formula set out in the ODBA, where the amount payable is equal to the difference in price (i.e., the increased drug price minus the drug benefit price) multiplied by the volume of drug product reimbursed under the Ontario drug program.

Reconsideration
The manufacturer may submit evidence to the executive officer that the amount calculated is not correct or that the manufacturer has complied with the ODBA, within 14 days of being served with the order, and the executive officer is required to reconsider the order.

Actions of executive officer after reconsideration
After reconsidering the order, the executive officer may affirm, rescind or vary the order.

Executive officer may act
Where the manufacturer has not complied with an order within 14 days of being served with it, or the order has been affirmed or varied, and the manufacturer still has not complied with it, the executive officer may issue a further order for compliance, or the executive officer may do one or both of the following until the manufacturer pays:

- remove a drug product's designation as a listed drug product;
- refuse to consider the manufacturer's other drug products for future designation as listed drug products or as interchangeable under the DIDFA, or for approval under the exceptional access program of the ODBA.

Limit on reconsideration
The manufacturer does not have another opportunity to have a further order reconsidered.

Required notice
The executive officer must give 30 days notice before the executive officer may refuse to consider the manufacturer's other drug products for designation as listed drug products, as interchangeable under the DIDFA, or for approval under the exceptional access program of the ODBA.

New section 11.5:
Rebates, etc.,
This section prohibits manufacturers from providing a rebate to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents for any drugs that are listed drug products or listed substance or for any drug in respect of which the manufacturer has made an application to the executive officer for designation as a listed drug product.

May not accept rebate
This section prohibits any person from accepting a rebate, directly or indirectly.

Executive officer may make an order
The executive officer may order manufacturers to pay the government an amount equal to any amount contrary to this section.

Calculation
The calculation of the amount owing to the government because of rebates is set out as follows:

- The expected cost for a drug or group of drugs provided by the manufacturer to the wholesaler or pharmacy is based on the drug benefit price for that drug(s) multiplied by the amount of product the wholesaler or pharmacy received from the manufacturer.
- The payment amount to government is the difference between the expected cost noted above and the actual cost to the wholesaler or pharmacy which includes the impact of any price reductions, free goods, or direct payments by the manufacturer, as examples.

Deemed drug benefit price
For the purpose of this rebates section, where a manufacturer has made an application to the executive officer for designation of a listed drug product, and the application is still under

consideration, the drug benefit price for the purpose of this section is the price that the manufacturer has submitted with its application.

Reconsideration
The manufacturer may submit evidence to the executive officer that the amount calculated is not correct or that the manufacturer has not provided a rebate, within 14 days of being served with the order, and the executive officer is required to reconsider the order.

Actions of executive officer after reconsideration
After reconsidering the order, the executive officer may affirm, rescind or vary the order.

Executive officer may act
Where the manufacturer has not complied with an order within 14 days of being served with it, or the order has been affirmed or varied, and the manufacturer still has not complied with it, the executive officer may issue a further order for compliance, or the executive officer may do one or both of the following until the manufacturer pays:

- If the product is a listed drug product, remove it's designation as a listed drug product;
- refuse to consider the manufacturer's other drug products for designation as listed drug products, as interchangeable under the DIDFA, or for s.8 approval under the ODBA.

Limit on reconsideration
The manufacturer does not have another opportunity to have a further order reconsidered.

Required notice
The executive officer must give 30 days notice before the executive officer may refuse to consider the manufacturer's other drug products for designation as listed drug products, as interchangeable under the DIDFA, or for approval under the exceptional access program of the ODBA.

Definition
"Rebate" includes but is not limited to currency, discounts, refunds, free goods or travel and any benefit set out in a regulation. Regulations may explain what is not a rebate. A rebate does not include a discount for prompt payment offered in the ordinary course of business.

Rules re sections 11.4 and 11.5
The executive officer is required to provide an order or a notice in a manner as set out in this section**.**

Same, publication of enforcement action
The executive officer may publish on the Ministry's website:
- the corporate names of manufacturers who are subject to a payment order or a measure to compel compliance;
- any information about the enforcement action that he or she thinks is appropriate.

No appeal
There is no appeal from a decision or action of the executive officer to order payment or compel compliance with a payment order, except as set out in the relevant sections.

SPPA does not apply
The executive officer's power to order payment or to compel compliance with a payment order is not subject to the *Statutory Powers and Procedure Act.*

Section 20

Minister and executive counsel to consult
This section gives the executive officer concurrent jurisdiction with the Minister to consult with stakeholders about concerns related to the ODBA and the DIDFA.

It also makes a technical change that reflects the fact that the Minister will no longer be responsible for making payments under the ODBA.

Section 21

Personal information
This section gives the executive officer concurrent jurisdiction with the Minister to collect, use, disclose or to enter agreements to collect, use or disclose personal information where necessary to administer the ODBA or to execute a purpose prescribed by the ODBA.

Section 22

Requirement to provide information; time and form
This section enables the executive officer to require a manufacturer, wholesaler, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies to provide the executive officer with information (other than personal information), at any time and in any form, in order to determine compliance with the ODBA or the DIDFA.

Compliance required
Those required to provide information are required to comply.

Publication
If the executive officer requires the provision of information at regular intervals, then the executive officer must publish the manner and form of information required on the Ministry website and may publish them in any other format that he or she considers appropriate.

Where Conflict
Information on the Ministry's website takes precedence over information in any other format, if there is a conflict.

Section 23

Examine books
This section amends the inspection section in the ODBA to permit inspectors to examine records held by operators of pharmacies, companies that own, operate or franchise pharmacies, including suppliers of listed substances, in addition to the previous ability of inspectors to examine records in the possession or under a control of a wholesaler or manufacturer for the purpose of determining the accuracy and completeness of a claim or of information required to be submitted under the Act, or in determining whether the wholesaler or manufacturer have complied with the ODBA and its regulations.

Section 24

Administrative change
This section reflects that the executive officer and not the Minister is responsible for claims for payment.

Refusal to submit
The administration of the DIDFA is added to this section for clarity.

Section 25

Repeal
Current section 16 of the ODBA is repealed as the ODBA is amended to include a more stringent scheme for regulating the prices manufacturers charge for drugs. Further, the provision that requires a manufacturer to provide the Minister with information about the production and sale of the drug product is deleted as a new section in the ODBA addresses information requirements.

The new section 16 pertains to drugs approved under the exceptional access program and provides as follows.

Unlisted drugs, special case
This section transfers from the Minister to the executive officer the power with respect to the exceptional access program to make the ODBA apply in respect of the supply of a drug, that is not a listed drug product, to an eligible person, where the executive officer is informed by a physician that the proper treatment of that person requires the administration of the drug.

Same
The drug benefit price for the supply of such a drug under this section is an amount to be determined by the executive officer, in accordance with the regulations.

Listed drugs, special case
This section transfers from the Minister to the executive officer the power to make the ODBA apply in respect of the supply of a listed drug benefit, under the exceptional access program, where a physician informs the executive officer that the proper treatment of an eligible person requires the administration of a drug that is listed but for which the conditions for payment have not been met (i.e. there are clinical criteria that apply to the supply of the listed drug product and they have not been met).

Notice to operator
This section changes the reference to a Minister's notice to that of the executive officer.

Retroactivity
This section empowers the executive officer to make the supply of a drug or listed drug product under the exceptional access program to apply retroactively to a time determined by the executive officer.

Section 26

Determination of drug benefit price
This amendment enables the executive officer to determine the conditions that must be met before a pharmaceutical product, including an extemporaneous preparation is designated as a designated pharmaceutical product, including the determination of the drug benefit price of the designated pharmaceutical product, and the formula for determining how the price is to be calculated. Formerly, the decisions with respect to the drug benefit price for designated pharmaceutical product were set out in regulation.

Section 22 does not apply
In this section, reference to section 16 is being removed as section 16 is repealed.

Publication
The executive officer must publish any conditions for listing or formulas for calculating drug benefit prices for designated pharmaceutical products on the Ministry website. He or she may also publish conditions and formulas in any other medium.

Where conflict
In the event of a conflict between the website and any other published material, the information posted on the Ministry's website prevails.

Section 27

This section make a number of changes to the regulation-making authorities set out in the ODBA, as follows.

Subsection 27(1)
Two regulation-making authorities are added to enable the LGIC to create regulations:

- defining professional services, including governing payments that may be made for such services and to whom and conditions to which the executive officer is subject in making payments for the professional services; and
- defining any word or expression used, but not defined, in the ODBA.

Subsection 27(2)
This section replaces the word "designated" with "prescribed." "Prescribed" has replaced "designated" in this Act as the word that denotes something in regulation.

Subsection 27(3)
This section removes the LGIC power to designate a product as a listed drug product on the Formulary. This section further removes the regulation-making authority to designate substances other than drugs that are listed substances. These powers have been transferred to the executive officer. Such listings no longer need to be done through regulation.

Subsection 27(4)
This amendment enables the LGIC to set conditions pertaining to the acquisition cost of a drug product.

Subsections 27(6), 27(7), 27(12), 27(16), 27(17), 27(22)
These amendments reflect the transfer of powers over the Ontario public drug programs from the Minister to the executive officer. They replace the term "the Minister" with "the executive officer."

Subsection 27(5)
This section permits the LGIC to regulate alternative payment mechanisms between the executive officer and pharmacy operators, for certain classes of eligible persons as specified.

Subsection 27(8)
This provision removes the authority to set the drug benefit prices for Formulary drugs by way of regulation. This power has been transferred to the executive officer. Listing no longer needs to be done through regulation.

Subsection 27(9)
This amendment permits the creation of a regulation that could set a maximum mark up of the drug benefit price, not just a percentage. It also reflects that payment of the price is to be now paid by the executive officer and not the Minister.

Subsection 27(10)
This section deletes the regulation-making power in respect of a provision that is being repealed (i.e. the dispensing fee for public hospital pharmacies).

Subsection 27(11)
This amendment empowers the LGIC to regulate not only the dispensing fee but also to set out conditions for payment of dispensing fees to operators of pharmacies.

Subsection 27(13)
This subsection repeals the LGIC's power to set the reporting obligations of drug suppliers to the Minister by regulation, as other amendments to the ODBA empower the executive officer to require reports in accordance with the ODBA.

Subsection 27(14)
This amendment deletes the regulation-making authority to designate listed drug products that do not require a prescription for sale as this power is transferred to the executive officer and no longer needs to be done through regulation.

Subsection 27(15)
The LGIC may make a regulation respecting how the drug benefit prices are to be calculated for the purposes of the exceptional access program under the ODBA.

Subsection 27(18)
This subsection empowers the LGIC to further clarify the definition of "rebate" by regulation.

Subsection 27(19)
This subsection reflects the concurrent jurisdiction that the Minister and the executive officer will have over the collection, use and disclosure of personal information.

Subsection 27(20)
This subsection removes the LGIC's power to make regulations in respect of designated pharmaceutical products and respecting the drug benefit price for such products. These powers have been transferred to the executive officer and no longer require a regulation.

Subsection 27(21)
This subsection removes the Minister's regulation-making authority to designate a product as interchangeable and the reference to the LGIC's authority to remove a designation as these powers are transferred to the executive officer and no longer require a regulation.

Section 28

Decisions about listing, delisting
In making a decision about designating a drug product as a listed drug product or removing the designation, the executive officer may consider anything he or she considers advisable in the public interest.

Delisting
The executive officer may remove a designation even if the conditions for listing in the regulations have not been breached, if it is advisable in the public interest.

Effect of breach of continuing conditions
Despite a breach of a condition set out in regulations, the drug product continues to be designated as a listed drug product until its designation is removed.

Advisors
The amendment to section 21 reflects the concurrent powers of the executive officer and the Minister to receive policy advice with respect to Ontario's public drug programs.

Drug Benefit price
The drug benefit price for a drug product when it becomes a listed drug product is the amount agreed to by the executive officer and the manufacturer, subject to conditions for listing in the regulations.

Executive officer's agreement
In deciding to agree to a drug benefit price, the executive officer may consider anything that is advisable in the public interest.

Request for change, criteria and compliance
A manufacturer may request a change in the drug benefit price. The request must comply with rules that may be established by the executive officer and posted on the Ministry's website..

The executive officer may publish any request requirements in any other medium. The website takes precedence over any other medium if there is a conflict.

Changing drug benefit price
The executive officer may change the drug benefit price of a drug product in consultation with the manufacturer, subject to the conditions set out in regulation, if the:

- manufacturer has submitted a request that complies with the executive officer's requirements; and
- executive officer considers it to be in the public interest to make the change.

Transitional and Clarification
The drug benefit price of a listed drug product will continue after this Act comes into force, until it is changed as permitted under the ODBA and the regulations. For clarity, the drug benefit price as set out prior to October 1, 2006 may be changed as permitted under the ODBA and the DIDFA**.**

Conditions of payment
The executive officer may designate specific situations in which there are special conditions for payment (i.e. specified clinical criteria that must be met in respect of the supply of a drug product or class of drug products for certain patients) and he or she must publish those conditions on the Ministry's website.

Part III: Commencement and Short Title

Section 29

Commencement
The sections updating the definition of interchangeability and the provision that repeals the separate dispensing fee for hospital pharmacies comes into force upon Royal Assent. The rest of the *Act* comes into force on October 1, 2006.

Section 30
Short title
The short title of this Act is the *Transparent Drug System for Patients Act, 2006.*